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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

See attached file.

Attachments

NRC_0230

To Whom its May Concern:
I am a board-eligible physician in my last year of a combined Nuclear Medicine and Diagnostic Radiology program.

Below are my answers to the questions posed in the NRC-2018-0230.

A. Tailored Training & Experience Requirements
Q 1. Are the current pathways for obtaining AU status reasonable and accessible?

- Yes. At my current institution and after discussion with peers, there is no unreasonable patient backlog at facilities performing RP therapies and pre-treatment imaging. There are a large number of AU eligible physicians and trainees in nuclear medicine, diagnostic radiology, and radiation oncology who can meet the demand for any additional AUs as new RP therapies come into practice.

Q 2. Are the current pathways for obtaining AU status adequate for protecting public health and safety?

- Yes. Postgraduate training and board examinations in nuclear medicine, diagnostic radiology, and radiation oncology ensure sufficient competency in medical physics, radiation safety, and radiation biology that other specialties do not.
- New radiopharmaceutical therapy dosimetry will likely be imaging based and will likely demand more training and experience with thernostic agents.

Q 3. Should the NRC develop a new tailored T&E pathway for these physicians?

- No. While a provider may have expertise in specific disease processes, surgical techniques, or conventional chemotherapies, an abbreviated AU pathway would not provide sufficient training in medical physics, radiation biology, or theranostic imaging interpretation and dosimetry to safely administer RP therapies.

Q 4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?

- There should be no limited AU status as there is no demonstrated need or record of safe administration of medical isotopes by individuals with abbreviated training.

Q 5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?

- There should not be a T&E pathway for specific categories of radiopharmaceuticals, as this would not ensure safe practice.

B. NRC's Recognition of Medical Specialty Boards
Q 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American

Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?

- To the best of my knowledge, no other specialty boards meet requisite expertise to provide minimal T&E for medical uses under 10 CFR 35.300.

Q 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

- Yes, the current criteria are sufficient.

C. Patient Access

Q 1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300?

- No. My opinion the most recent report from the American Board of Nuclear Medicine as provided to the NIH at the recent Theranostics Consensus Conference on November 8-9, 2018, as presented by Dr. Iagaru (http://snmmi.files.cms-plus.com/Theranostics%20Consensus%20Conference_Nov%209.pdf).

Q 2. Are there certain geographic areas with an inadequate number of AUs?

- Not to my knowledge. Nevertheless, relaxing established safety regulations would potentially harm patients. Existing professional societies such as the American College of Radiology and the Society of Nuclear Medicine and Molecular imaging can help identify regions at risk and aid in physician recruitment to these areas.

Q 3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals?

- No.

Q 4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine?

- No.

D. Other Suggested Changes to the T&E Regulations

Q 1. Should the NRC regulate the T&E of physicians for medical uses?

- Yes, NRC must regulate the T&E of physicians for medical uses. This ensures the safe practice.

Q 2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

- No.

Q 3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

- The NRC should continue to monitor the evolving fields of RP therapy and theranostics. Additional formal training and requisite experience in theranostic imaging interpretation and radiation dosimetry will be required.

Thank you for your consideration.